UNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND

ESTATE OF HELEN WHOLEY, by and through its Co-Executor, Timothy Wholey,

Plaintiff,

v. C.A. No. 03-109T

MICHAEL O. LEAVITT,[1] Secretary, United States Department of Health and Human Services, and COORDINATED HEALTH PARTNERS, INC.,

Defendants.

MEMORANDUM AND ORDER

ERNEST C. TORRES, Chief Judge.

Helen Wholey died on March 22, 1999 and, pursuant to 42 U.S.C. § 1395ff(b)(1)(A), her estate has appealed the denial of Mrs. Wholey's application for Medicare Part B reimbursement for the cost of a stairlift device placed in her home. The defendants are the Secretary of the United States Department of Health and Human Services ("HHS"), which administers the Medicare program, and Coordinated Health Partners, Inc. ("Coordinated"), a health

[1]Pursuant to the automatic substitution provision in Fed. R. Civ. P. 25(d)(1), Secretary Leavitt hereby replaces former Secretary Tommy G. Thompson as a defendant in this matter.

maintenance organization ("HMO") that is a Medicare contract carrier.[2]

For the reasons hereinafter stated, the Court hereby affirms the Secretary's decision.

Facts and Travel

The record[3] shows that Helen Wholey was a Medicare Part B beneficiary (See Compl. ¶ 14; see Answer ¶ 14) and that she was covered by traditional fee-for-service Medicare until July 1, 1997, when she changed her coverage to a managed care option administered by Coordinated.

In 1996, Mrs. Wholey was 87 years old and lived in a two-story house in Narragansett, Rhode Island. (See Admin. R. 441.) Her bedroom and bathroom were located on the second floor, (see id. at 439-40), but the record does not indicate anything else about the home's configuration.

Mrs. Wholey suffered from a number of medical conditions, including osteoporosis, osteoarthritis, atrial fibrillation,

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[2]Carriers, such as Coordinated, are private entities with whom Medicare contracts "to make initial reimbursement determinations and to administer payments" to beneficiaries. See United States v. Lahey Clinic Hosp., Inc., 399 F.3d 1, 4 (1st Cir. 2005), cert. denied, __ U.S. __, 126 S. Ct. 339, 163 L. Ed. 2d 51 (2005).

[3]In the proceedings below, the Secretary adopted the statement of facts set forth in the Estate's memorandum of law in exchange for the Estate waiving the Secretary's failure to produce a transcript of a previous hearing. (See Admin. R. 2, 20.) Except where otherwise noted, the facts set forth by the Court are drawn from that statement. (See id. at 17-22.)

vertigo, a recent hip fracture, and impaired vision. According to her physician, Dr. Jefferys Bandola, and her physical therapist, Kathleen Kolb, these conditions prevented Mrs. Wholey from safely climbing stairs on her own. Accordingly, Dr. Bandola and Ms. Kolb recommended that Mrs. Wholey obtain a stairlift device for her home. A stairlift (sometimes called a "stairglide") is a motorized device that operates along a track affixed to the side of a staircase and can convey an individual up or down a flight of stairs while the individual remains seated. (See id. at 127-30, 142, 440.)

Mrs. Wholey rented a stairlift, which was installed in her home in September 1996. She paid an installation fee of $700.00 and, thereafter, she paid rental charges of $95.00 to $125.00 per month. (See id. at 64-79, 441-44.)

In 1999, Mrs. Wholey sought reimbursement from Medicare in the amount of $3,387.00 for the two and one-half year period during which she had the stairlift. She sought approximately half of that amount directly from the Medicare program and the other half through Coordinated because each provided coverage during part of that period.

Both of Mrs. Wholey's claims were denied and she appealed the denials. Her appeals were consolidated into a single proceeding before an administrative law judge ("ALJ"), who conducted two

hearings during which he heard testimony and received exhibits. Among the exhibits submitted by the Estate were:

- an August 22, 1996, open letter from Dr. Bandola stating that:

> Mrs. Helen Wholey has been my patient for many years. Mrs. Wholey's medical conditions include; myocardial infarction, congestive heart failure, and a hip fracture. It has become increasingly more difficult for her to climb stairs in her home. I have advised her to research the possibility of having a stair lift installed in her home.

(id. at 139);

- a second open letter from Dr. Bandola, dated January 24, 1997, stating that:

> Mrs. Helen Wholey has been my patient for several years. Her medical conditions include; osteoporosis, osteoarthritis, atrial fibrillation, vertigo due to labrynthitis and a history of a fractured hip. Mrs. Wholey lives in her own home and manages quite well with the assistance of home care services. It is Mrs. Wholey's wish to remain in her home however obstacles such as staircases are presenting a problem. Her bedroom and bathroom are located on the second floor. Due to her declining overall medical condition, together with impaired vision and a general weakness, she is unable to navigate the stairway safely.
>
> I have advised her family that a motorized stair glide would safely convey Mrs. Wholey to the second floor and allow her to continue living independently.
>
> At this time the stair glide has been installed in Mrs. Wholey's home. She is now

> able to live independently in a much safer environment.

(id. at 439);

- a November, 1996, open letter from physical therapist Kolb describing Mrs. Wholey's condition and stating that:

> Due to these conditions, her mobility is impaired by thoracic kyphosis, shortness of breath, poor endurance, permanent balance impairment, and general muscle weakness. She has also had a history of vision problems which occasionally contribute to this impaired mobility. Although physical therapy has enabled her to improve her gait and strength to an extent, Mrs. Wholey continues to need assistance with her mobility to ensure her safety at home.
>
> Mrs. Wholey's bedroom and bathroom are located on the second floor of her home. Due to Mrs. Wholey's medical status, she is unable to climb or descend a flight of stairs without serious risk of injury. Therefore it was necessary to install a "stair glide," which is essentially a motorized chair that ascends and descends her staircase, in order to enable her to remain at home. She has learned to use the stair glide independently and safely, and I feel that this has been an effective and medically necessary solution to a potentially hazardous situation.

(id. at 440);

- a June 29, 1999, letter from the president of the American Occupational Therapy Association ("AOTA") expressing the association's view that stairlifts should be covered by Medicare because they are "assistive technology devices" and are properly employed in the

practice of occupational therapy, (id. at 221), along with materials describing the scope of the practice of occupational therapy (id. at 136-38, 222-24, 335-37); and

- various scholarly articles and texts concerning the use of "assistive technology" devices within the practice of occupational therapy (id. at 127-30, 144-216, 225-334).[4]

On April 27, 2000, the ALJ issued a decision denying coverage, (see id. at 80-89), and, on June 19, 2000, the Estate sought review by HHS' Departmental Appeals Board ("DAB"), (see id. at 51-79). Because HHS was unable to produce a transcript of the first hearing before the ALJ, at which Mrs. Wholey's son testified, the DAB agreed to adopt the Estate's statement of facts in place of the missing transcript. (Id. at 2, 20.) Nevertheless, the DAB denied the Estate's request for review, (see id. at 1-3; see Compl. ¶ 3; see Answer ¶ 3), and the Estate brought this suit.

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[4]According to these sources, occupational therapists consider the use of assistive technology to be within the scope of their practice and to be helpful to many patients. They refer to the Assisted Technology for Individuals with Disabilities Act, 29 U.S.C. § 3002, which defines "Assistive Technology Device" as "[a]ny item [or] piece of equipment . . . that is used to increase, maintain, or improve functional capabilities of individuals with disabilities," (Admin. R. 306), including, *inter alia*, stairlifts, (id. at 129, 158), computer screen magnifiers, (id. at 310), velcro closures on clothing, (id. at 158), TDD/TTY telephones, (id.), garage door openers, (id. at 208), and microwave ovens, (id.).

Standard of Review

42 U.S.C. § 1395ff(b)(1)(A) provides for judicial review of final HHS determinations denying Medicare benefits, in accordance with the standards set forth in 42 U.S.C. § 405(g), which apply to review of Social Security Administration decisions. See Currier v. Thompson, 369 F. Supp. 2d 65, 68 (D. Me. 2005). Under those sections, the reviewing court must determine "whether the final decision is supported by substantial evidence and whether the correct legal standard was used." Seavey v. Barnhart, 276 F.3d 1, 9 (1st Cir. 2001) (citing, *inter alia*, 42 U.S.C. § 405(g)). While questions of law are reviewed *de novo*, id. (citations omitted), the Secretary's findings of fact, "if supported by substantial evidence, shall be conclusive," 42 U.S.C. § 405(g).

"[S]ubstantial evidence has been defined as 'more than a mere scintilla . . . such relevant evidence as a reasonable mind might accept as adequate to support a conclusion,'" Brown v. Apfel, 71 F. Supp. 2d 28, 30 (D.R.I. 1999) (quoting Richardson v. Perales, 402 U.S. 389, 401, 91 S. Ct. 1420, 28 L. Ed. 2d 842 (1971)), aff'd, 230 F.3d 1347 (1st Cir. 2000), and "[t]he determination of substantiality must be made upon an evaluation of the record as a whole," id. (citing Irlanda Ortiz v. Sec'y of Health and Human Servs., 955 F.2d 765, 769 (1st Cir. 1991)). The reviewing court "must avoid reinterpreting the evidence or otherwise substituting its own judgment for that of the [Secretary]." Id. at 30-31

(citing Colon v. Sec'y of Health and Human Servs., 877 F.2d 148, 153 (1st Cir. 1989)); accord Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512, 114 S. Ct. 2381, 2386, 129 L. Ed. 2d 405, 415 (1994) ("TJU") ("Our task is not to decide which among several competing interpretations best serves the regulatory purpose.").

When an agency has duly promulgated a regulation or interpretive rule designed to clarify an ambiguity in its regulations or in the statute that it administers, the Court owes that interpretation "substantial deference" as long as it is reasonable. See Gonzales v. Oregon, __ U.S. __, __, 126 S. Ct. 904, 914-15, 163 L. Ed. 2d 748, 766 (2006) (citations omitted); see Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-44, 104 S. Ct. 2778, 2781-82, 81 L. Ed. 2d 694, 702-04 (1984). An interpretation is reasonable if it "reflects a plausible construction of the plain language of the statute and does not otherwise conflict with Congress' expressed intent." Rust v. Sullivan, 500 U.S. 173, 184, 111 S. Ct. 1759, 1767, 114 L. Ed. 2d 233, 249 (1991) (citing Chevron, 467 U.S. at 842-43, 104 S. Ct. 2778, 81 L. Ed. 2d 694). On the other hand, an agency interpretation in the form of an opinion letter, policy statement, or manual that is not subject to the public hearing and advertising requirement mandated by the Administrative Procedure Act is "entitled to respect," but only to the extent that it has the "power to persuade." Christensen v. Harris County, 529 U.S. 576,

587, 120 S. Ct. 1655, 1662-63, 146 L. Ed. 2d 621, 631-32 (2000) (citing Skidmore v. Swift & Co., 323 U.S. 134, 140, 65 S. Ct. 161, 89 L. Ed. 124 (1944)) (additional citations omitted).

Deference to an agency's judgment is "all the more warranted" when that judgment involves interpretation of the agency's own regulation that "concerns 'a complex and highly technical regulatory program,' in which the identification and classification of relevant 'criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" TJU, 512 U.S. at 512, 114 S. Ct. at 2387, 129 L. Ed. 2d at 414-15 (quoting Pauley v. BethEnergy Mines, Inc., 501 U.S. 680, 697, 111 S. Ct. 2524, 115 L. Ed. 2d 604 (1991)). The First Circuit has said that "the classification of medical equipment for [Medicare] reimbursement purposes is the sort of technical question that generally benefits from HCFA's expertise and experience." Warder v. Shalala, 149 F.3d 73, 84 (1st Cir. 1998)(citations omitted) cert. denied, 526 U.S. 1064, 119 S. Ct. 1455, 143 L. Ed. 2d 541.

An agency decision may only be deemed reasonable if the agency "articulate[d] a logical basis for [its] decision[], including a rational connection between the facts found and the choices made." Skubel v. Fuoroli, 113 F.3d 330, 336 (2d Cir. 1997) (citing, *inter alia*, Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43, 103 S. Ct. 2856, 77 L. Ed. 2d 443 (1983)). However, the degree of deference to which an agency

decision is entitled "diminishes as issues become more law-bound and less moored to administrative expertise." Stowell v. Sec'y of Health and Human Servs., 3 F.3d 539, 544 (1st Cir. 1993) (citation omitted).

Analysis

I. Medicare - the Statutory and Regulatory Framework

"Medicare is a federally-funded health insurance program for the elderly and disabled." TJU, 512 U.S. at 506. The Secretary of Health and Human Services is responsible for determining which specific procedures and supplies Medicare will cover, consistent with the scope and nature of benefits described in the statute, see TJU, 512 U.S. at 507 (citation omitted); see Warder, 149 F.3d at 75. In administering the program, the Secretary is authorized to issue "substantive regulations and interpretive rules," Warder, 149 F.3d at 75 (citing 42 U.S.C. § 1395hh); accord TJU, 512 U.S. at 506-07 (citation omitted) but the Secretary has delegated some of his responsibilities to the Health Care Financing Administration ("HCFA"). See Estate of Aitken v. Shalala, 986 F. Supp. 57, 58-59 (D. Mass. 1997) (citations omitted).[5]

A. National Coverage Determinations

One of the tasks that HCFA performs is to provide guidance with respect to what items and/or services are covered by Medicare.

[5]In 2001, HCFA changed its name to the Centers for Medicare and Medicaid Services ("CMS").

When there is substantial disagreement within the medical community regarding the efficacy and/or safety of a particular item, or where there is disagreement among Medicare-contracted carriers as to whether a particular item should be a covered, HCFA may issue a National Coverage Determination ("NCD"), Aitken, 986 F. Supp. at 59, which is "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under [the Medicare statute]," 42 U.S.C. §§ 1395y(1)(6)(A), 1395ff(f)(1)(B).

Before 2003, NCDs were binding on carriers and others in the decision making process below the ALJ level, but they were not binding on ALJs unless they were issued pursuant to the provision of 42 U.S.C. § 1395y(a)(1)(A) that excludes from coverage any item or service that is "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member". See 42 C.F.R. § 405.860(a)(1)-(2).[6]

A beneficiary may challenge the validity of an NCD by filing a complaint with the DAB, see 42 U.S.C. § 1395ff(f)(1)(a)(iii), in which case the DAB's decision "constitutes a final agency action . . . subject to judicial review," id. at (f)(1)(A)(v); see also Estate of Aitken v. Shalala, 986 F. Supp. 57, 59 (D. Mass. 1997) (describing extent of courts' power to review NCDs).

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[6]Now, all NCDs are binding on ALJs. See 42 C.F.R. § 405.860(a)(4).

B. Part B Coverage

The Medicare program is divided into several parts. Part B, for those who choose to enroll in it, covers "medical and other health services," 42 U.S.C. § 1395k(a)(1), see Warder v. Shalala, 149 F.3d 73, 75 (1st Cir. 1998), which are defined to include, *inter alia*, "durable medical equipment" ("DME") and "prosthetic devices . . . which replace all or part of an internal body organ," see 42 U.S.C. § 1395x(s)(6),(8). However, as already noted, items and services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" and "personal comfort items" are expressly excluded from coverage. Id. at § 1395y(a)(1)(A), (a)(6).

When coverage for a particular item or service is disputed, the claimant bears the burden of proving his or her entitlement to benefits. Keefe v. Shalala, 71 F.3d 1060, 1062 (2d Cir. 1995) (citing Friedman v. Sec'y of the Dept. of Health and Human Servs., 819 F.2d 42, 45 (2d Cir. 1987)); Smith v. Thompson, 210 F. Supp. 2d 994, 1000 (N.D. Ill. 2002) (citing same).

1. Durable Medical Equipment

The Medicare statute enumerates some of the items that qualify as DME, but the list is not exhaustive. More specifically, 42 U.S.C. § 1395x(n) provides, in pertinent part:

> [t]he term "durable medical equipment" includes iron lungs, oxygen tents, hospital beds, and wheelchairs

> (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient's home . . . whether furnished on a rental basis or purchased . . . With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.

The regulations also provide a non-exhaustive list of items that qualify as DME, which tracks the items listed in the statute. See 42 C.F.R. § 410.38(a). In addition, the regulations contain a functional definition of DME as "equipment . . . that-- (1) [c]an withstand repeated use; (2) [i]s primarily and customarily used to serve a medical purpose; (3) [g]enerally is not useful to an individual in the absence of an illness or injury; and (4) [i]s appropriate for use in the home." 42 C.F.R. § 414.202.

While neither the statute nor the regulations refer specifically to stairlifts, HCFA has issued NCDs indicating that "stairway elevators" are not considered DME and, therefore, are not covered under Part B. See 54 Fed. Reg. 34555, 34596-99 (Aug. 21, 1989); (see Admin. R. 406, 411.) These NCDs may be found in section 60-9 of the Medicare Coverage Issues Manual and they state:

Elevators	Deny -- convenience item; not primarily medical in nature (§ 1861(n) of the Act[7]

. . .

[7]Section 1861(n) of the Social Security Act is codified at 42 U.S.C. § 1395x(n). It is the statutory "definition" of DME.

Stairway Elevators	Deny -- (See Elevators.) (§ 1861(n) of the Act).	

54 Fed. Reg. at 34596-99; (Admin. R. 406, 411.)

2. Prosthetic Devices

The statute includes "prosthetic devices," within the category of "medical and other health services" for which Medicare coverage is afforded. The description of prosthetic devices is:

> prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens[.]

42 U.S.C. § 1395x(s)(8). The definition in the regulations essentially tracks the statutory language. See 42 C.F.R. § 414.202.

II. The ALJ's Decision

Before the ALJ, the estate argued that a stairlift was DME within the meaning of 42 U.S.C. § 1395x(n) (subsection 1861(n) of the Social Security Act) or, alternatively, that it was a prosthetic device within the meaning of 42 U.S.C. § 1395x(s)(8) (subsection 1861(s)(8) of the Social Security Act). (Admin. R. 104-25.)

Although the ALJ referred to the literature regarding assistive technology as "tend[ing] to show that the cited medical sources regard the stair glide as being medically appropriate and

beneficial to individuals such as the beneficiary," (id. at 87-88) the ALJ found that a stairlift was not DME because the Estate failed to satisfy two prongs of the functional definition test set forth in 42 C.F.R. § 414.202. (Id. at 88-89.) More specifically, the ALJ found that the Estate failed to establish that a lift was "primarily and customarily used to serve a medical purpose" and that it was "not generally useful without regard to illness or injury." (Id. at 89.)

In addressing the "medical purpose" prong of the test, the ALJ acknowledged the letters from Dr. Bandola and Ms. Kolb but stated that they did not "contain[] precise clinical findings or functional estimates." (Id. at 87.) Although the ALJ mentioned the NCD excluding "stairway elevators" from the category of DME as a determination that "[did] not seem to be unreasonable," he expressly stated that the NCD was "not binding" on him. (Id. at 88.) Instead, the ALJ based his determination on a finding that the "record [did] not establish" that a stairlift is "primarily and customarily" used for medical purposes. (Id.)

With respect to the "not generally useful" prong, the ALJ stated:

> It appears that many healthy senior citizens, who have no injury and no illness, would welcome the use of a stair glide in their home [sic]. Anyone can purchase a stair glide, without a doctor's prescription, and anyone could use it. There is no data presented to establish that the stair glide is used for primarily for [sic] medical reasons more than as a convenience or a personal comfort item.

Id.

The ALJ did not address whether the stairlift qualified as a prosthetic device. (See id. at 83-89.)

In seeking review by the DAB, the Estate argued that the ALJ erred in:

(1) ignoring the "large body of evidence . . . showing that a stairlift has a 'medical purpose,'" (id. at 22-37); [emphasis added]

(2) requiring "numerical support for coverage of stairlifts." Presumably, this refers to the ALJ's comment about the lack of "precise clinical findings or functional estimates" in the letters from Dr. Bandola and Ms. Kolb. (id. at 37-41);

(3) "failing to completely disregard the . . . NCD [stating that "stairway elevators" are not DME] as legal authority, so that the NCD improperly influenced the . . . decision," (id. at 41-42); and

(4) considering the "generally not useful" prong of 42 C.F.R. § 414.202's functional definition of DME even though the carrier and others had not done so, (id. at 44-46).

In the memorandum of law that it submitted to the DAB, the Estate made a passing reference to the ALJ's failure to address whether the stairlift qualified as a prosthetic device, (id. at 22), but it made no further mention of that issue, (see id. at 17-

47). The Estate's memorandum also asserted that the "stairway elevators" NCD "never had any basis in health science," implying that it should be invalidated. (Id. at 42-44.)

The DAB denied the Estate's request for review and the Estate brought this appeal. (Id. at 1-3.)

III. The Estate's Appeal

In this appeal, the Estate does not challenge the validity of 42 C.F.R. § 414.202, which contains the functional definition of DME on which the ALJ relied.[8] What the Estate challenges is the ALJ's finding that stairlifts do not satisfy the regulation's requirements. The gist of the Estate's argument is that the ALJ erred by:

(1) improperly relying on the "Stairway Elevators" NCD, which the Estate contends is invalid;

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[8]It might be argued that the regulation is an unreasonable interpretation of the statute because the "primarily and customarily used to serve a medical purpose" requirement appears to categorically exclude from coverage some items that may serve a legitimate medical purpose in a particular case if they more often have non-medical uses. Furthermore, the requirement that an item must be "generally . . . not useful to an individual in the absence of an illness or injury" may be read to exclude items that are expressly included within the statutory definition of DME, such as hospital beds, which have features that may be useful to individuals who do not suffer from illness or injury. Conversely, it might be argued that Medicare is not obliged to cover every procedure or device that may be used for medical purposes in a particular case and that interpreting the statute in that manner would require coverage of items such as swimming pools that are most often used for other purposes and have considerable value independent of their utility in treating illness or injury.

(2) putting the burden on the Estate to prove coverage

(3) finding that the Estate failed to establish that the stairlift was primarily and customarily used for a medical purpose;

(4) addressing whether the stairlift was "[g]enerally [] not useful to an individual in the absence of an illness or injury" despite the fact that this question had not been addressed by the carrier or others who participated in the denial of the Estate's claim;

(5) finding that the stairlift was generally useful in the absence of illness or injury even though there was no such evidence in the record; and

(6) concluding that stairlifts are excluded from Medicare coverage, *per se*, rather than confining his decision to the individual claim before him.

A. Reliance on the NCD

The Estate's appeal focuses primarily on what it argues is the invalidity of the "Stairway Elevators" NCD and the ALJ's reliance on the NCD in making his decision. However, there are two flaws in that argument.

First, the validity of the NCD is not an issue properly before this Court because the Estate has not exhausted the administrative remedies provided for challenging an NCD. Under 42 U.S.C. §

1395ff(f)(1)(A)(iii), one who seeks to challenge an NCD, first, must file a complaint with the DAB. The Estate has failed to do that and the passing reference to the NCD's validity in its memorandum seeking DAB review of the ALJ's decision does not satisfy that requirement.

Even if the Estate had exhausted its administrative remedies, the validity of the NCD would not be an issue because, contrary to the Estate's assertion, the ALJ did not rely on the "stairway elevators" NCD in reaching his decision. As already noted, although the ALJ referred to the NCD as "not unreasonable," he expressly recognized that it "was not binding" on him and he based his decision on what he found to be the Estate's failure to satisfy the requirements in 42 C.F.R. § 414.202 that a device be "primarily and customarily used to serve a medical purpose" and that it "[g]enerally is not useful to an individual in the absence of an illness or injury." (Admin. R. 88-89.) In making those findings, the ALJ was not required to pretend that the NCD did not exist or to ignore it. He was entitled to consider it recognizing that is was not binding on him and that is exactly what he did.

B. The Burden of Proof

The Estate's argument that the ALJ erred by requiring the Estate to prove coverage rather than requiring the Secretary to rebut Mrs. Wholey's claim misapprehends who has the burden of proof. It is well-established that the burden of proving coverage

is on the beneficiary. See Keefe v. Shalala, 71 F.3d 1060, 1062 (2d Cir. 1995) (citation omitted); see Smith v. Thompson, 210 F. Supp. 2d 994, 1000 (N.D. Ill. 2002) (citation omitted). Therefore, under 42 C.F.R. § 414.202, the Estate had the burden of proof, at least with respect to the requirement that a stairlift must be "primarily and customarily used to serve a medical purpose."

C. The Primary and Customary Medical Purpose Requirement

The Estate argues that, even if it had the burden of proving that the stairlift was primarily and customarily used to serve a medical purpose, it carried that burden. The thrust of the Estate's argument is that mobility enhancement is a medical purpose, as evidenced by the fact that Medicare specifically covers wheelchairs and seatlifts. The Estate also points to the evidence that professionals in the fields of medicine, physical therapy, and occupational therapy consider the use of assistive technology, such as stairlifts, to be within the scope of their practices.

That argument would be persuasive if the Regulation's definition of DME focused on the unique facts of each individual case. In Mrs. Wholey's case, the letters from Dr. Bandola and Ms. Kolb indicate that, due to Mrs. Wholey's physical infirmities, a stairlift was necessary to enable her to get from one floor of her house to another, and that for her its primary purpose was to assist her in dealing with a medical condition.

However, the Regulation's definition of DME does not focus on the unique facts of each individual case. Instead, it takes a categorical approach that focuses on the nature of the item and the purposes for which it, ordinarily, is used rather than the use to which it may be put in a particular case. Thus, 42 C.F.R. § 414.202(2) requires that a device be "primarily and customarily used to serve a medical purpose." 42 C.F.R. § 414.202(2) (emphasis added). It also requires that the device "[g]enerally is not useful to an individual in the absence of an illness or injury." 42 C.F.R. § 414.202(3) (emphasis added).

Although the wisdom of a categorical approach may be debatable, the approach is not unreasonable. While, in a particular case, the categorical approach may not produce the desired result, it provides predictability and uniformity in distinguishing between devices that do and do not qualify as DME. Consequently, the adoption of a categorical approach is a policy judgment that the Secretary has discretion to make as long as it is not at odds with the statute.

Here the Secretary's judgment does not conflict with what appears to be Congress' intent in enacting the Medicare statute. Although Congress has expressly included motorized vehicles that may be used as wheelchairs among the items listed as DME in § 1395x(n), it has not included stairlifts even though that subsection has been amended twice since the NCD excluding "stairway

elevators" from coverage was issued. See Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251; Omnibus Reconciliation Act of 1990, Pub. L. 101-508, 104 Stat. 1388. Other sections of the statute also have been amended numerous times. See Deficit Reduction Act of 2005, Pub. L. No. 109-171, 120 Stat. 4; Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066; Social Security Act Amendments of 1994, Pub. L. No. 103-432, 108 Stat. 4398; Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 312.

It also might be argued that, since stairlifts transport individuals vertically, they are the functional equivalent of motorized wheelchairs that transport individuals horizontally but there is nothing so irrational about affording coverage to motorized wheelchairs but not stairlifts that would warrant the conclusion that Congress' omission of stairlifts was inadvertent.

Consequently, the issue presented is whether the ALJ's decision that Mrs. Wholey's stairlift did not satisfy the requirements of 42 C.F.R. § 414.202 is supported by substantial evidence, bearing in mind that the Estate bore the burden of proving coverage. As already noted, most of the evidence presented focused on the usefulness of a stairlift to Mrs. Wholey and not the broader question of whether stairlifts, in general, are primarily and customarily used to serve a medical purpose. The only evidence dealing with stairlifts, in general, were the various materials

describing the use of "assistive technology" devices that are "helpful" to persons with physical impairments in the practice of occupational therapy. Those materials are not sufficient to establish that stairlifts primarily serve a medical purpose, especially since they include such devices as garage door openers and microwave ovens in the category of assistive technology.

In short, the record supports the ALJ's finding that stairlifts do not satisfy the "primary and customary" prong of the test set forth in 42 C.F.R. § 414.202. See Murphy v. Sec'y of Health and Human Servs., 62 F. Supp. 2d 1104, 1108 (S.D.N.Y. 1999) (Where a claimant bears the burden of proof on a disputed coverage issue, the lack of such proof constitutes "substantial evidence" on which an ALJ can base a denial).

D. The "Generally Not Useful" Requirement

The Estate argues that, in finding that a stairlift is "generally not useful in the absence of an illness or injury" the ALJ impermissibly "switched issues" because the carrier and others who participated in the denial of benefits did not consider this issue but, rather, relied solely on the "stairway elevator" NCD. Alternatively, the Estate argues that, even if it was proper for the ALJ to consider the "generally not useful" prong of the DME test, his findings are not supported by substantial evidence.

The issue-switching argument lacks merit because the Estate's appeal to the ALJ was grounded on the contention that the "stairway

elevator" NCD was invalid and that a stairlift was DME. Thus, the Estate had ample opportunity to argue and, in fact, did argue that a stairlift satisfies the "generally not useful" requirement that is one of the criteria for DME set forth in 42 C.F.R. § 414.202.

The more difficult question is whether there is substantial evidence in the record supporting the ALJ's finding that stairlifts are "generally not useful in the absence of an illness or injury," because "many healthy senior citizens, who have no injury and no illness, would welcome the use of a stair glide in their home [sic]," (Admin. R. 88), and because "[a]nyone can purchase a stair glide, without a doctor's prescription, and anyone could use it," (id.).

The answer to that question turns on who has the burden of proof with respect to whether a device, generally, is or is not useful and what evidence is required in order to satisfy that burden. The fact that a claimant bears the ultimate burden of persuasion in establishing coverage does not necessarily mean that the claimant bears the burden of production with respect to every factor relevant to the determination. It is, at least, arguable that the burden should be on the Secretary to present evidence that a device "primarily and customarily used for a medical purpose" is useful to persons who do not suffer from illness or injury. Since the Secretary would be the one claiming that the device is useful to healthy individuals, requiring a claimant to present evidence

that the device is not makes little sense and would impose a virtually impossible burden of proving a negative. Furthermore, evidence that a device is useful to healthy individuals is presumably more readily accessible by the Secretary. See La Montagne v. Am. Convenience Prods., Inc., 750 F.2d 1405, 1409-10 (7th Cir. 1984) (explaining that burden-shifting analysis in employment discrimination cases arises from premise that the burden of production with respect to a given issue should fall on the party most likely to have access to evidence relevant to that issue) (citations omitted); Lawton v. Nyman, 357 F. Supp. 2d 428, 436 (D.R.I. 2005) (the burden of presenting evidence to support a contention generally should fall upon the party to whom the evidence "is more readily available") (citing Pidcock v. Sunnyland Am., 854 F.2d 443, 448 (11th Cir. 1988)); accord 1 Jack B. Weinstein & Margaret A. Berger, Weinstein's Federal Evidence § 301.06[1] (2d ed. 2006) (acknowledging the "evidentiary consideration[]" of "allocating the burden of production to the party most likely to have access to the pertinent evidence") (citations omitted).

However, assuming arguendo that the Secretary bears the burden of production, it is unclear how far the Secretary would have to go in order to carry that burden. In some cases, the Secretary clearly would be required to present testimony or exhibits establishing non-medical uses for the item in question. However,

in this case, the ALJ's finding, arguably, is supportable in the absence of such evidence because the usefulness of stairlifts for non-medical purposes appears to be common knowledge.

This Court is not aware of any authority dealing with these questions but it need not decide them because, as previously stated, the ALJ's finding that stairlifts are not "primarily and customarily used to serve a medical purpose" is supported by the record and that finding is sufficient to support his decision that stairlifts are not DME.

E. Prosthetic Devices

As already noted, the ALJ did not address the Estate's contention that a stairlift is a "prosthetic device" within the meaning of 42 U.S.C. § 1395x(s)(8) (subsection 1861(s)(8) of the Social Security Act). However, the Estate has waived that failure as a ground for appeal because it did not squarely raise the issue in its memorandum of law to the DAB and did not brief the issue in its memoranda to this Court.

In any event, it is clear on the face of the statute that a stairlift is not a prosthetic device. The statute defines a prosthetic device as one "which replace[s] all or part of an internal body organ" and it provides examples such as colostomy bags and other devices that are attached to the body and function as substitutes for portions of the anatomy that have been removed or have ceased to function. See 42 U.S.C. § 1395x(s)(8). By

contrast, a stairlift is an assistive device that is not attached to the body and does not replace or perform the function of an internal body organ. Rather, like other assistive devices such as computer screen magnifiers, a stairlift helps an individual to overcome physical limitations in order to perform a particular task--in this case, the task of climbing stairs.

The definition advocated by the Estate would make virtually every device that is useful in performing a physical task a prosthetic device covered by Medicare. That would be contrary to the commonly accepted definition of a "prosthetic device," as an artificial device to replace a missing part of the body," see Merriam-Webster's Third New International Dictionary of the English Language 1822 (1993), and contrary to Congress' apparent intent in enacting the Medicare statute.

Conclusion

For all of the foregoing reasons, the ALJ's decision denying the Estate's claims is affirmed.

IT IS SO ORDERED:

Ernest C. Torres
Chief Judge

Date: November 9 , 2006